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CFHealthHub

Participant Information Sheet

Invitation

We would like to invite you to take part in a long- term project into CF care. Before you decide we would like you to understand why the research is being done and what it will involve. Please read the following information sheet carefully before you decide whether you wish to take part.

What is the purpose of the study?

Taking preventative medications for Cystic Fibrosis (CF) helps keep lungs in a better condition and reduces hospital admissions for patients with CF (PWCF). Researchers have developed a website called CFHealthHub, where PWCF can view feedback on how they take their medication (adherence) which is automatically sent from chipped nebuliser devices, and also receive support to self-manage CF.

In this study, we will develop CFHealthHub to present adherence data to your local CF team and support CF centres in the UK to use this information. The data may be used as part of normal care and lead to changes in how the CF team support patients. The information will also help us to understand the differences in CF care across the UK and as we understand how some centres support their patients to achieve a high level of adherence to medication we can support other services by sharing best practice. PWCF will also be given the option to contribute their CFHealthHub data to future research studies related to CF, which could result in being offered new treatments.

Why have I been invited?

You have been selected because you have CF and attend a CF centre in the UK. You also use, or may start to use, a nebuliser which is compatible with CFHealthHub. You may have previously participated in the CFHealthHub RCT (ref 17/LO/0035).

Do I have to take part?

No, taking part is voluntary. It is up to you to decide to join the project or not. We will describe the project in this information sheet.

If you agree to take part, we will arrange an appointment where you will be asked to sign a consent form and we will provide more information about the study. The appointment can take place at your local CF centre or we can arrange a home visit. Due to the COVID-19 pandemic, consent appointments may be conducted over the telephone to allow you to participate without the need for you to come into hospital. If you decide to take part we will send a letter to your GP to inform them you are taking part in a research project.

If you do not wish to take part, you will not be asked to do anything else. This will not affect the quality of care you receive from your CF centre, but they may ask you whether you'd like to take part again at a later date if they feel you may benefit from using a chipped nebuliser.

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What happens if I am new to CFHealthHub?

Consent appointment

The consent appointment may take approximately 30 – 60 minutes. If you already use a chipped nebuliser (e-track or ineb) and CFHealthHub, there is no need to change what you are already doing and this will make your consent appointment shorter. You will be given the opportunity to discuss the study and be asked to sign the consent form, and provide some information about your health and how you manage your CF on a questionnaire.

If you do not currently use a chipped nebuliser (e-track) or CFHealthHub, we will provide you with the new equipment. The chipped nebuliser is like the usual e-Flow, but has a small chip in it, which lets it transfer information about your nebuliser usage, via the Qualcomm hub to CFHealthHub. If you use an ineb device then you will continue to use this device as normal. At the moment, ineb data will not be displayed in real time and requires a member of your care team to upload the data into CFHealthHub.

At your consent visit, or shortly after, either a member of your CF team or member of the central CFHH team trained in behaviour change intervention, will demonstrate the features of the CFHealthHub website, which is designed to help you build successful treatment habits. You will also receive your log in details.

CFHealthHub can display your medication prescription, create graphs of your treatment use, help you to set goals and personalised action plans, and provide information on CF which is tailored to you. This appointment will be with a member of your local CF team or the central team and may take place at your CF centre or in your home, or over the telephone if appropriate.

During the COVID-19 pandemic we are looking into alternative ways to deliver e-track nebulisers and download data from ineb nebulisers so you will be able to participate without needing to visit a hospital. You may be contacted by the CFHH team to arrange and discuss this.

What happens if I was involved in the CFHealthHub RCT (REC reference 17/LO/0035)?

Consent appointment

If you are participating, or have participated, in the CFHealthHub Randomised Controlled Trial (RCT), then you will complete the consent appointment, as detailed above, but you will not be given a new CFHealthHub account or any new equipment.

What happens next if I received the CFHealthHub RCT intervention? After your consent appointment there will be no further action for you to take until your involvement in the trial ends in June 2019. When your involvement in the trial ends, you will be able to continue using your CFHealthHub account and your chipped device as normal. You will keep the same CFHealthHub log in details; however you may start to see some additional features in CFHealthHub.

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What happens next if I did not receive an intervention (control group)?
If you took part in the CFHealthHub RCT but were in the control group i.e. did not receive the intervention, then you will be able to start accessing CFHealthHub after your consent appointment. You can continue using your chipped device as normal.

New and Existing CFHealthHub participants

During the study
You will be asked to continue to use your chipped nebuliser and CFHealthHub and contribute your data. This includes data which is generated from using CFHealthHub, such as;

- Adherence data
- CFHealthHub usage data e.g. how often you visit the site
- Information added related to self-managing CF such as action plans and questionnaires about your health behaviour

Your local CF team or the central team may work with you to support your adherence to treatment and use CFHealthHub as part of routine care, for example using the information in clinics or during inpatients stays. To ensure that CFHealthHub is useful from the beginning of the project we will retain any information in CFHealthHub for existing users and add information to CFHealthHub related to CF, held within;

- Medical records (such as your prescription, lung function or body weight)
- CF Registry data (pseudomonas status, lung function)
- Your current chipped nebuliser

As you are seen in routine care and supported with adherence we will ask you to provide some more information on questionnaires about adherence to medication.

If you indicated on your consent form that you would like to participate in future research you may be contacted regarding new studies and be asked whether you would like a new treatment.

How will this data be used?
Throughout the study you are in control of the level of data you contribute to the project and who can see this data, for example on CFHealthHub you can turn off sharing your personal data with your CF team.

As a minimum, we would ask for consent to statements 1-13 on the consent form which would allow us to group your data with other CF patients at your centre and present this information to CF centres in the UK. This will support CF centres to understand the standard of care at each site. We would also share data* with CF Registry to provide greater understanding of the health of the CF population.

*(*data- where information which identifies you e.g. your name, date of birth, is removed and replaced with an ID number. This makes your identity extremely difficult to obtain outside of the research team and is a widely-used technique within the NHS and research studies).*

If you are willing to participate in future research projects which are hosted by the Data Observatory, this would mean you can be included in studies which look at your data but does not impact your care (consent statement 14). Finally if you consent to be included for 'selection' for future research, you may be selected by chance to receive an invitation for a new treatment or therapy. You can decide against participating in the new study without any consequences. However, if you are not selected and the new research does not require any change to your care or data collection then your data may still be used but you will not be informed. This is an important part of our project which will make CF research easier, less expensive and ensure that research is less disruptive to patients (consent statement 15).

Sheffield Teaching Hospitals NHS Foundation Trust (STH) is the sponsor for this study based in the United Kingdom, and will act as the data controller for this study. The day to day running of the study is delegated to The University of Sheffield (UoS) and CFHealthHub is hosted by the University of Manchester. Together Sheffield Teaching Hospitals NHS Foundation Trust and The University of Sheffield and the University of Manchester will be using information from you and/or your medical records in order to undertake this study. This means that we are responsible for looking after your information and using it properly. Sheffield Teaching Hospital will retain information you provide in the study for 5 years and destroy it after the study has finished.

Who can I contact if I need help using the new equipment?

If you experience any problems using the equipment in this study either a member of the research team at your CF centre or within the central CFHH team, will be able to support you. This may involve communication outside of the normal care you receive from the CF centre.

What are the possible disadvantages and risks of taking part?

The main disadvantage would be to give up your time to attend the consent appointment.

What are the possible benefits of taking part?

Participants in the study may provide data which leads to changes in the CF care they receive at their own centre, or helps us to understand more about CF care across the UK. Some people find feedback available in CFHealthHub useful to understand their condition or form habits to take their medication. Participants who are selected to participate in new studies may benefit from the treatment or therapy offered.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. We will keep the information you have given up to the time you withdraw but will not collect any new information or contact you again regarding the study. Participants can withdraw their consent to any part of the study mentioned above. If you withdraw from the study entirely, we will check that you are still happy for us to link your data to CF Registry data. You do not need to do this however if you don't want to.

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Who do I contact…?

For more information;

You can contact the local investigator to discuss any aspect of the study or to let them know you are interested; their details are listed below.

To complain;

If you have any cause to complain about any aspect of the study the normal National Health Service complaints mechanisms are available to you. If you have any complaints or concerns, please contact your local investigator in the first instance.

<INSERT local investigator name and contact details>

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). Our Data Protection Officer /The Sponsor's Data Protection Officer is Peter Wilson and you can contact them by phone (0114 2265153) or email (peteriwilson@nhs.net).

Will my taking part in this study be kept confidential?

Where possible, and in accordance with the consent you provide, your data will be kept confidential and we will remove information which identifies you. To monitor the study, the consent form, which will include your name and signature, will be sent to researchers at the University of Sheffield by post. Your CF team will be aware of your participation in CFHealthHub, however, they may not be aware of your participation in future research.

Data confidentiality

All contact details, along with questionnaire and research data collected from you will be stored on a secure server at the University of Sheffield (Prospect). Prospect complies with the Data Protection Act and uses industry standard techniques to provide security. Only authorised users can access this data.

CFHealthHub will also store your personal information e.g. name, contact details, NHS number and any information you use to personalise the website, such as pictures or action plans, alongside data regarding nebuliser use (sent digitally from your chipped nebuliser). Before you can access CFHealthHub, you will be reminded of CFHealthHub security. All CFHealthHub data is stored on a secure server at the University of Manchester site. CFHealthHub complies with the Data Protection Act and follows best practice guidelines on security and information governance. All data transferred to and from the web and mobile app platforms uses encrypted channels. Only authorised users will be able to access CFHealthHub, and you will be given your own username and log in details.

Data will be securely exported from CFHealthHub for the purposes of analysis by the research team at the University of Sheffield.

Data will be shared with the CF Registry, and will be encrypted and sent securely.

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You can contact information governance at Sheffield Teaching Hospitals by email (sth.infogov@nhs.net).

You can find out more about how we use your information at:
https://www.sheffieldclinicalresearch.org/for-patients-public/how-is-your-information-handled-in-research/

What will happen to the results of the research study?
This project will lead to developments to the CFHealthHub software, and increase the data available at your CF appointments, as well as improve care locally and nationally. Information will be available on the University of Sheffield website and via research articles in journals or conferences. The results of studies supported through the CFHealthHub Data Observatory will be presented separately elsewhere.

The intellectual property which is developed as part of the Data Observatory and the wider ACtiF programme (REC reference 17/LO/0035, NIHR reference RP-PG-1212-20015) will be managed by the National Institute for Health Research.

Who is organising and funding the research?
The project is being carried out by a team researchers from the School of Health and Related Research at the University of Sheffield, Sheffield Teaching Hospital NHS Foundation Trust and the University of Manchester. The CFHealthHub project is supported by the NHS England through Commissioning for Quality and Innovation (CQUIN) funding.

Who has reviewed the study?
This study has been reviewed and approved by the London - Brent Research Ethics Committee (Reference number: 17/LO/0032)

Thank you for taking the time to read this information sheet.